510(k) Premarket Notification
PharmaJet, Inc.
PharmaJet Needle-free Injection System
-510(k) Summary- K110456

MAR - 2 2011

Date Prepared: 6 December 2010

Device Name – Proprietary , Common, Classification, and Panel

Proprietary:	PharmaJet 0.1 ml Needle-free Injector System
Common:	Injector, Fluid, Non-Electrically Powered
Classification:	21 CFR 880.5430; Product Code KZE, Class II
Device Panel:	General Hospital

Application Information

Applicant:	PharmaJet, Inc. 400 Corporate Circle, Suite N Golden, CO 80401
Telephone:	(303) 526-4278
FAX:	(303) 526-4052
Establishment Registration:	3004977013
Owner/Operator:	9063237

Submission Correspondent Information

Contact:	Michael J. Ryan, R.A. Manager
Telephone:	(303) 526-4278 Ext. 4172

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Reason for Premarket Notification

New Device

Predicate Devices

PharmaJet 0.5 ml Needle-free Injection System, K081532
Terumo 1 cc Allergy Syringe, K980796

Description of the Device

The PharmaJet 0.1 ml Needle-free Injection System (PharmaJet System) is a compact, spring-loaded needle-free hypodermic injection system. The PharmaJet System consists of an injector; a reset station; a single use, sterile disposable filling adapter; and, a single use, sterile, disposable needle-free syringe. The components of the system may be sold separately for replacements as they are used. The components of the PharmaJet System are unique and cannot be used with any other needle-free system.

An injector is placed in the reset station and the lid is depressed to reset the spring in the injector. A health care worker puts a filling adapter into a vial of liquid medicine or vaccine. A Needle-free syringe is placed into the filling adapter, the liquid is drawn into the Needle-free syringe and is slightly over filled. The filled Needle-free syringe is removed from the adapter and the plunger is broken off and discarded. The Needle-free syringe is placed into the injector with a ¼ turn to the right, which positions the plunger so that a 0.1ml dose is ready for use. The Needle-free syringe is placed against the injection site; gentle pressure is applied until the inner housing stops. This action allows the trigger to be released. By depressing the trigger the spring is released and the plunger moves forward into the needle-free syringe barrel discharging the contents. Once the injection has been performed, the Needle-free syringe is properly disposed of and a new syringe may be filled, injector reset, and the system again prepped for use.

Injector

The Injector is a reusable compact spring-actuated needle-free hypodermic injector consisting of the body, inner body/safety collar, trigger, and spring. The injector is made with stainless steel and injection molded amorphous thermoplastic polyetherimide.

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Needle-free syringe

The Needle-free syringe is a sterile, single use, transparent, disposable, polypropylene container consisting of the barrel to hold 0.1ml of medicine or vaccine, a plunger to discharge the medicine or vaccine through a small diameter orifice at the forward end of the barrel, and a silicone seal on the plunger to prevent leakage of the medicine or vaccine rearward.

Reset Station

The Reset Station is used to prepare (reset) the spring, within the injector, for an injection. The reset station is made with stainless steel and injection molded amorphous thermoplastic polyetherimide.

Filling Adapter

The filling adapter allows the needle-free syringe to be filled from medicine or vaccine storage vials. The filling adapter, which does not contact the patient, is made of injection-molded polycarbonate.

Indication for Use

The PharmaJet Needle-free Injection System is intended to deliver various medications and vaccines intradermally by means of a narrow, high velocity fluid jet, which penetrates the skin and delivers the medicine or vaccine into the dermis. Healthcare providers who routinely administer injections may use the PharmaJet Needle-free Injection System. It may be used for adults and children. It can also be used by patients authorized by their physicians to self inject, or have other individuals administer injections of prescribed medication.

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Technological Characteristics

Characteristic	PharmaJet 0.1 ml Needle-free Injection System	PharmaJet 0.5 ml Needle-free Injection System	Terumo Allergy Syringe
Actuation feature	Trigger	Trigger	Standard piston syringe
Trigger safety	Yes	Yes	Not Applicable (NA)
Spring life cycle	20,000	20,000	NA
Method of power	Mechanical spring	Mechanical spring	Standard piston syringe
Method of spring reset	External resetting device	External resetting device	NA
Method of medicine and/or vaccine transfer	Filling adapter	Filling adapter	Fixed hypodermic single lumen 27 gauge, 1/2"or 3/8" needle, with an intradermal bevel.
ISO 21649: 2006 compliance	Yes	Yes	NA
Volume:	0.1ml	0.5ml	0.1 – 1.0 ml
Material	Body – polypropylene Plunger – polycarbonate Seal – silicone rubber	Body – polypropylene Plunger – polycarbonate Seal – silicone rubber	Unknown
Orifice Diameter	0.007"	0.009"	NA
Tip Ring Diameter	0.419"	0.529"	NA
Disposable	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Sterilization Method	Electron beam radiation	Electron beam radiation	Unknown

Discussion of Non-clinical Tests

The purpose of the Bench Testing for the PharmaJet Needle-free Injection System was to establish that the system meets the requirements of the PharmaJet 0.1ml Product and Engineering Specifications with regard to robustness for customer needs and meet the essential requirements of *ISO21649:2006 Needle-free injectors for medical use —Requirements and test methods.*

The following tests have been successfully completed:

- Temperature, storage temperature, free-fall, vibration, shock, dose accuracy, life cycle, performance profile upper and lower acceptance limits and emitted noise testing according to *ISO21649:2006 Needle-free injectors for medical use —Requirements and test methods*
- Needle-free Syringe Irradiated Dose Test for Robustness
- Microbial Ingress Testing

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Animal testing was performed to demonstrate substantial equivalence to an intradermal injection using the Terumo 1cc Allergy syringe. The test results indicate that the PharmaJet 0.1 ml Needle-free Injection System is substantial equivalence to the Terumo 1 cc Allergy Syringe with regards to the three primary endpoints: bleb diameter, depth of penetration based on dermal height, dye dermal contact area, and the secondary calculated endpoint of skin volume occupied by the dye.

Maximum irradiated sterility dose test was done on the needle-free syringe to demonstrate material robustness and microbial ingress testing on the Filling Adapter was done to demonstrate that the Filling Adaptor can be disinfected using common disinfection techniques.

Biological testing conducted demonstrate that the PharmaJet Needle-free Syringe and Filling Adapter meet the requirements for safe short term exposure,

Functional testing after Gluteraldehyde-based and peroxide-based high level disinfection show no degradation of performance or damage to Injectors or Reset Stations.

Conclusion

Pre-clinical testing and bench testing have shown that for intradermal delivery with needle-free jet injection the PharmaJet 0.1 ml Needle-free Injection System is as effective, as safe, and performs as well as, or better than one of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pharmajet, Incorporated
C/O Mr. Jeff D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, North Carolina 27709

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Re: K110456
Trade/Device Name: PharmaJet 0.1ml Intra-dermal Needle-Free Injection System
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powder Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: February 14, 2011
Received: February 16, 2011

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110456

Device Name: PharmaJet, Inc.,
PharmaJet 0.1ml Intra-dermal Needle-free Injection System

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/3/4

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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